June 23, 2000

Hon. Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Department Of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Rule on Medicare Payment for Upgraded Durable Medical Equipment and Its Effect on Small Entities; 65 Fed. Reg. 24,666 (April 27, 2000)

Dear Administrator DeParle:

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to advocate the views of small business before federal agencies and Congress. Among other things, the Chief Counsel of Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)[1] to monitor agency compliance with the RFA. The Chief Counsel of Advocacy is also authorized to appear as *amicus curiae* in any action brought in court to review a rule, and is allowed to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.[2] The Chief Counsel appreciates the opportunity to comment on the above-referenced regulation relative to the potential impact on small businesses.

On April 27, 2000, the Health Care Financing Administration (HCFA) published a proposed regulation that would amend the Medicare rules to permit Medicare suppliers to furnish upgraded durable medical equipment (DME) on an assignment basis. Under the proposed regulation, Medicare payment would be made to the supplier as if the DME were non-upgraded DME; and the beneficiary/consumer purchasing or renting the upgraded DME would pay the supplier an amount equal to the difference between the supplier's charge for the DME upgrade and the amount paid by Medicare. The proposal also contains certain consumer safeguards to deter fraud and abusive sales practices.

The proposal was born out of the Balanced Budget Act of 1997 (BBA) to allow Medicare beneficiaries the same opportunity as customers with private insurance to apply the limits of their benefits against upgraded equipment that better suits their needs. Medicare is structured so that the benefit only covers DME that is adequate and effective to meet the medical needs of the beneficiary, but will not pay extra for convenience or luxury features, nor more than the applicable fee schedule amount. This rigid policy means that

[1] 5 U.S.C. § 601 et seq.
[2] *Id.* at § 612

Medicare will not pay, for instance, for an ultralight wheelchair for the elderly woman who takes care of her wheelchair-bound husband. The standard wheelchair is adequate for the needs of the husband, but the wife cannot lift or push the heavy standard chair. Similarly, Medicare may not pay for the total electric hospital bed, but the wife may be unable to turn the cranks to adjust the manual-type bed. The proposed regulation would allow this husband and wife to obtain a lightweight chair or the electric bed using the Medicare payment for the standard items and making up the difference in price themselves. This is a good policy that could greatly improve the quality of life and care for many Medicare beneficiaries, and therefore, should be implemented as soon as possible.

The Problem

HCFA recognizes that there could be a small population of unscrupulous suppliers in the market that could defraud consumers by employing bait-and-switch tactics or otherwise taking advantage of consumers by using the DME upgrade provision to supply expensive products that are not needed. To cure this problem, HCFA is proposing that consumers have thirty days to reconsider their decision to upgrade a product, whereupon they could return the product to the supplier. Once the product has been returned, the supplier would have to replace the upgraded product with a standard one. The problem with this proposal is twofold: it overlaps and is inconsistent with existing consumer protection laws, thereby adding confusion to the overall regulatory scheme; and more importantly, from the perspective of the Office of Advocacy, it is overly burdensome for small DME suppliers.

Small Business Burden

In order to understand the burden of the thirty-day return policy, HCFA must first understand and take into consideration the normal business practices of small DME suppliers and the market for DME supplies. Does HCFA understand, for instance, that DME suppliers—especially small ones—must special order many of the custom or upgraded products? This means that the products cannot simply be returned to the manufacturer if the customer decides after thirty days that they would prefer a standard product. Moreover, a product with thirty days of wear and tear could hardly be sold as a new item—assuming there were a buyer for a custom product in the first place. The unintended consequence of HCFA's thirty-day return policy may be that suppliers simply decide to avoid purchasing such items altogether out of fear that the product can be returned for as long a period as thirty days. In turn, the effects of the 30-day policy could ripple over to beneficiaries who would have very limited access to upgraded products. This result would nullify the entire purpose of the regulation.

Consumer Protection Laws

In HCFA's proposal, the agency seeks comment on other approaches to beneficiary protection.[3] The Federal Trade Commission has had rules in place since 1972 that require sellers, when selling at places other than their regular places of business, to inform buyers of their right to cancel the sale within three business days and receive a full refund when the purchase price is $25.00 or more. In addition, the seller must furnish the

[3] 65 Fed. Reg. at 24,668.

buyer with a summary of the buyer's cancellation rights and two copies of the cancellation form. The rule is commonly known as the "Cooling-Off Rule." When it last sought public comment on changing certain provisions of the cooling-off rule in 1994, the FTC concluded that the rule provides substantial benefits to consumers without imposing unreasonable costs on sellers. In addition, most (if not all) states have adopted their own versions of the FTC rule—with an average 3-5 day cooling-off period.

While the FTC cooling-off rule contains certain enumerated exceptions, those exceptions need not all be included in HCFA's final rule.[4] An FTC-type standard would be more than adequate for dealing with issues like buyers' remorse, undue or coercive sales pressure and bait-and-switch tactics. The 3-5 day standard would be in conjunction with other beneficiary protections like the disclosure form that requires providers to describe the standard item to consumers before they opt for an upgrade, hefty sanctions for unscrupulous suppliers, and the recordkeeping requirements.[5] It is Advocacy's recommendation that HCFA adopt a similar standard.

Regulatory Flexibility Act Requirements

The agency's regulatory flexibility analysis is inadequate on its face. It is not clear, for instance, whether or not the agency certified the rule pursuant to section 605 of the RFA. The agency states, "we do not believe that any one supplier will incur a significant burden."[6] Section 605 allows agencies to avoid an in-depth initial regulatory flexibility analysis of a regulation if the agency head certifies that a regulation will not have a significant economic impact on a substantial number of small entities. Under section 605, an agency must provide a factual basis for such certification. HCFA's statement, quoted above, does not constitute a certification, a factual basis or an analysis.

If the agency alters the return policy, then the agency may be able to certify the regulation. First, the agency should address its technically deficient certification by including the certification language (contained in section 605 of the RFA) it the text of the proposed regulation. In addition, the RFA analysis could be improved to provide greater transparency.

The paperwork requirements do not seem unreasonable, but the proposal does not include estimates (or even guesstimates) on the total burden associated with the paperwork requirements. It seems that some sort of estimate of costs should be present in order for the agency to be able to provide a factual basis for its certification. HCFA states that it cannot predict the number of forms individual suppliers will be completing. HCFA also states that it cannot determine which suppliers will accept assignment versus non-

[4] For example, the FTC cooling-off rule does not cover sales that: 1) are made entirely by mail or telephone, 2) are the result of prior negotiations at the sellers permanent business location where the goods are sold regularly, 3) are needed to meet an emergency, etc.

[5] As an added measure of beneficiary protection, HCFA proposes to add section 414.231(c) which would require "that suppliers must meet before they are allowed to sell upgraded DME to Medicare beneficiaries on an assigned basis." 65 Fed. Reg. at 24,667. Advocacy assumes that HCFA intends for suppliers to meet beneficiaries, but HCFA's statement is somewhat ambiguous—stating that suppliers must meet, but not indicating with whom. This provision should be clarified.

[6] *Id.*at 24,670.

assignment type claims. There is no burden associated with unassigned claims because the beneficiary simply pays for the DME item and submits the claim him or herself—obviating the need for any paperwork on the part of the supplier. Advocacy wonders if the number of assigned claims under the current Medicare rules can be used as a baseline for determining the number of assigned claims in the instant regulation.

In the proposal, HCFA solicits comment on certain alternatives to reduce burden or enhance consumer protection. Those alternatives include: 1) a phase-in approach focusing initially on certain kinds of DME for which there is the greatest demand like ultralight wheelchairs and total electric hospital beds; and 2) distinguishing between an upgraded item that might be covered as medically necessary from one that is a slightly different item for which there was no Medicare fee schedule amount.[7]

Advocacy defers to the industry on these questions. However, it seems that a phase-in approach might prove confusing, cumbersome, or even more costly (in terms of training, administrative cost, etc.) if other DME items are added later. In addition, it seems that suppliers may even have an opportunity to sell more upgraded DME products because Medicare is picking up part of the tab. Beneficiaries who might desire upgraded equipment, but could not afford it entirely on a private pay basis, may now be inclined to purchase or rent the equipment. Finally, beneficiaries would likely benefit from the application of this regulation to all DME items.

As for the second question, it is interesting how the minor (but important) variations in products keep coming up as a problem in relation to HCFA's coding of DME items.[8] In any event, it seems that payment is more certain in the case of the former provision where consumers can obtain full payment for the item with the additional features. Surely, this is preferable to suppliers and consumers. In the latter case, the consumer may be unable to pay for even a minor upgrade which benefits neither the supplier nor the consumer. Advocacy can only offer this cursory analysis of HCFA's alternatives. The industry is better positioned to respond to these issues.

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[7] HCFA states that in the case of the former, the consumer could obtain payment for the item with additional features, while in the latter case, Medicare would pay only for the item without features and the beneficiary would pay, fully at their own expense, for the difference between the supplier's charge for the upgraded item and the Medicare payment for the non-upgraded item. HCFA contemplates that it might be appropriate to consider whether upgrade covers minor variations in an item of DME where the same code is used to bill for the item as the standard item. *Id.* at 24,668.

[8] These variations were an issue in HCFA's recent proposal for a demonstration project on competitive bidding for durable medical equipment. The argument Advocacy and the industry made to OMB during the paperwork clearance process was a company bidding on a single wheelchair code may not be able to meet the clinical needs of all beneficiaries who require variations in parts, support and features/options within the same code (e.g., low seat heights for beneficiaries with short legs, or swing-away arms for stroke patients). In other words, not all suppliers can provide the necessary level of specialization within a particular wheelchair code, thereby limiting beneficiary choice. The other part of the argument was that a supplier that has based its business on providing very basic wheelchairs with no elements of specialization might not be able to compete effectively in a competitive bidding environment. The whole point was that wheelchairs were inappropriate for inclusion in the demonstration because of the degree of variation within the codes.

Thank you for your consideration of these comments. Please do not hesitate to contact our office if you have any questions, 202-205-6945.

Sincerely,

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